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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,636	02/21/2007	Balkrishen Bhat	X-16329	5083

25885 7590 10/02/2008

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
10/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/559,636	BHAT ET AL.	
	Examiner	Art Unit	
	Sean R. McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-96* is/are pending in the application.

4a) Of the above claim(s) *94-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I and SEQ ID NO: 81 in the reply filed on 9/10/08 is acknowledged. It is noted that applicant has indicated the election of SEQ ID NO: 81 as a "species election", however it is clear from the restriction requirement mailed 8/13/08 that the Sequences are considered different inventions and it was indicated that the separation of the sequences was a further restriction of group I.

Claims 94-96 and sequences other than SEQ ID NO: 81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/10/08.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: Applicant has claimed benefit of applications 10/618,553 and 10/823,448 under 35 USC 119(e). These applications are not provision applications.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 72-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al [US 6,335,194] or Bennett et al [US 6,838,283], or Bennett et al [US 7,288,530] or Bennett et al 6,077,709] and Tuschl et al [US 2004/0259247] and Vickers et al [The Journal of Biological Chemistry Vol. 278(9):7108-7118, 2003] and Morrissey et al [US 2003/0206887] and Arnold et al [US 6060456].

The invention is as clearly set forth in the claims.

The Bennett et al patents will be referred to collectively in the body of the instant rejection since the disclosure of the patents are very similar.

The Bennett et al patents are all drawn to antisense compounds that target Survivin encoding nucleic acids. Bennett et al all teach antisense compounds that comprise nucleotides 1-18 of the instant SEQ ID NO: 81 [SEQ ID NO:24 of 6,077,709 and SEQ ID NOS 33 and 73 in the remaining Bennett patents]. Bennett et al have therefore taught an accessible region of Survivin. Bennett et al teach all of the recited nucleobase, sugar, and backbone modifications recited in the instant claims except for LNA and alternating phosphorothioate/phosphodiester linkages (see paragraphs 32-45 of 6,335,194, for example). Bennett et al teach conjugates (see paragraph 38 of 6,335,194, for example). The modifications and conjugates are all described as providing benefits for antisense function. Pharmaceutical formulations are taught by Bennett (see paragraph 51 of 6,335,194, for example). The Bennett patents all teach that Survivin antisense molecules are utilized to treat cancer. It is disclosed in the patents that antisense acts to sequence specifically inhibit its target nucleic acid/gene. Bennett et al do not teach siRNA.

Tuschl et al have taught siRNA compounds are more efficient and safer that prior art compounds and that siRNA functions to sequence specifically inhibit a target gene (see paragraph 8 for example). At paragraphs 15 and 16 it is disclosed various modifications that may be used in the base, sugar and backbone of siRNA compounds. At paragraphs 29 and 30, for example, it is taught that siRNA can be used to inhibit gene function in cells or organisms and that targeting genes associated with cancer are desired. At paragraphs 31-33, for example, pharmaceutical compositions are disclosed.

Tuschl et al have taught that overhangs [canonical of the instant invention] are preferred over blunt ended siRNA

Vickers et al have taught that RNA interference can be considered an antisense mechanism. Vickers et al have taught that, in general, activity of siRNA correlated with the activity of RNase H-dependent antisense oligonucleotides. In other words, if an antisense is functional for a specific target one can have a reasonable expectation that an siRNA targeted to the same target will also be functional.

Morrissey et al have taught siRNA targeted to HBV. However, Morrissey et al is relied upon to teach the modifications recited in the instant claims. Morrissey et al provide a detailed description of modifications that may be used in siRNA including all those instantly recited except for alternating phosphorothioate/phosphodiester linkages. Morrissey et al also teach pharmaceutical formulations for siRNA. Morrissey (see for example paragraphs 50, 56, 59, 62, 67-71, 92, 88 and 225 but note that the document comprises teaching of modifications throughout). Morrissey et al also teach both blunt ended and siRNA with overhangs.

Arnold et al teaches many modifications that can be used in antisense, but is relied on in particular for the teaching of alternating phosphorothioate/phosphodiester linkages.

The prior art has therefore taught an antisense compound that targets the same target as the instantly claimed siRNA. The prior art has taught that siRNA is more efficient and safer than antisense compounds. The art has taught that once an RNase H-dependent antisense oligonucleotide has been shown to be functional that, in

general, a siRNA targeted to the same target will also be effective. That would appear to meet any reasonable expectation of success question. The prior art has shown all of the modification recited in the instant claims for use in siRNA or in antisense. Since the prior art has taught that siRNA functions as an antisense mechanism it would be reasonable to assert that any modification used in an antisense would have a reasonable expectation of functioning in a siRNA compound.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry
Primary Examiner
Art Unit 1635

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